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APPLICATION NO.	FILING DATE	Marc C. Albertsen	1148D	5787
10/021,657	12/14/2001		EXAMINER	
7:	590 05/11/2004		KUBELIK	, ANNE R
Patricia A. Sweeney 1835 Pleasant St. West Des Moines, IA 50265-2334			1638	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/021,657	ALBERTSEN ET AL.				
Office Action Summary	Examiner	Art Unit				
-	Anne R. Kubelik	1638				
The MAILING DATE of this communication	appears on the cover shee	t with the correspondence address				
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REI THE MAILING DATE OF THIS COMMUNICATIO - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a - If NO period for reply is specified above, the maximum statutory per - Failure to reply within the set or extended period for reply will, by sta Any reply received by the Office later than three months after the mearned patent term adjustment. See 37 CFR 1.704(b).	N. 1.136(a). In no event, however, m reply within the statutory minimum of the control of the co	ay a reply be timely filed of thirty (30) days will be considered timely. MONTHS from the mailing date of this communication. ne ARANDONED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 8	December 2003.					
20) This action is FINAL 2b) This action is non-final.						
Since this application is in condition for allo	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice und	er <i>Ex parte Quayle</i> , 1935	C.D. 11, 453 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>1-15, 19-22, 27-34</u> is/are pending	in the application.					
4) Of the above claim(s) 2.5,8,19-22 is/are	withdrawn from conside	ration.				
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1,3,4,6,7,9-15 and 27-34</u> is/are re	jected.					
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction at	nd/or election requiremer	ıt.				
Application Papers						
The appointment is objected to by the Exal	miner.					
9) ☐ The specification is objected to by the Examiner. 10) ☑ The drawing(s) filed on 14 December 2001 is/are: a) ☑ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to	o the drawing(s) be held in a	beyance. See 37 CFR 1.03(a).				
Depletement drawing sheet(s) including the co	prrection is required if the dr	awing(s) is objected to. See 37 CFR 1.121(d).				
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119	roign priority under 25 II	S.C. § 119(a)-(d) or (f).				
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of: 1.☐ Certified copies of the priority documents have been received.						
— Cultura de situado que	ments have been receive	d in Application No				
2. Continued copies of the priority documents of the	priority documents have	been received in this National Stage				
3. Copies of the certified copies of the application from the International B	ureau (PCT Rule 17.2(a)).				
* See the attached detailed Office action for	a list of the certified copie	es not received.				
OUT THE SHAPE STATES						
Attachment(s)	4) 🗀 Int	erview Summary (PTO-413)				
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-94)	, a. Pai	per No(s)/Mail Date				
3) Information Disclosure Statement(s) (PTO-1449 or PTO/S	SB/08) り 🗀 🗥	tice of Informal Patent Application (PTO-152) her:				
Paper No(s)/Mail Date		D. J. C. Danas No. /Mail Data 304				

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DETAILED ACTION

1. Applicant's election with traverse of group 1 (claims 1-15, 27-29, 31 and 34) in the response filed 5 February 2004 and SEQ ID NO:7 in the response filed 8 December 2003 is acknowledged. The traversal is on the ground(s) that group II uses the nucleic acid of Group I and that these two groups were together in the parent application. This is not found persuasive because group II is drawn to a method of using plants produced by the method of claim 12, which is a method of impacting fertility comprising impacting the SBM200 gene. These plants can be produced by methods other than using the nucleic acid of claim 1, for example by mutation of genes that affect the expression of the nucleic acid of claim 1. Thus, the plants used in the methods of Group II do not necessarily comprise the same nucleic acids as the plants of group I and the two groups are not coextensive.

Because claims 30 and 32-33 are drawn to vectors comprising the elected nucleic acid, they will be examined with the elected invention, and the restriction between them and group I is withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2, 5 and 8 are drawn to non-elected sequences. Claims 2, 5, 8 and 19-22 are withdrawn from consideration as being drawn to non-elected inventions.

2. The copies of the PTO-892 and PTO-1449 from parent application 09/670,153 do not serve as PTO 1449s for the instant application. The information on the 892 is not even on a 1449 form, and the 1449 from the parent does not have the application number from the instant application on it and is a photocopied version of the signed 1449 from the parent. New 1449s should be submitted. The information on the forms submitted has not been considered.

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This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Sequence identifiers are missing from the Brief Description of Figure 6.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth herein. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

- 4. The abstract is not descriptive of the instant invention, which is a nucleic acid from maize that affects male fertility, vectors, plant cells and plants comprising it and a method of using it to affect male fertility in plants. A new abstract is required that is clearly indicative of the invention to which the claims are directed. The abstract of the disclosure should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.
- 5. The title of the invention is not descriptive of the instant invention, as above. A new title is required that is clearly indicative of the invention to which the claims are directed. Note that titles can be up to 500 characters long.

Claim Objections

6. Claims 3, 10-15, 28-30 and 32-33 are objected to because of the following informalities:
In claims 3 and 13, "NOs." should be replaced with --NOs:--.
In claims 10-11, 14-15, 29-30 and 33, there should be comma before "wherein".

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In claims 12-13 and 32, "comprising" should be replaced with --, wherein the method comprises--.

There should be a comma after "27" in claim 28, line 1, and claim 32, line 2. In claim 32, line 2, "control" should be plural.

Claim Rejections - 35 USC § 112

- 7. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 8. Claims 1, 3-4, 6-7, 9-15, and 27-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a multitude of nucleic acids that hybridize to SEQ ID NO:7 or nucleic acids encoding SEQ ID NO:8 and that "mediate male fertility". In contrast, the specification only describes a coding sequence from maize that comprises SEQ ID NO:7. Applicant does not describe other nucleic acids encompassed by the claims, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

The description of the function of the nucleic acid is not specific, and therefore not descriptive.

Hence, Applicant has not, in fact, described nucleic acids that hybridize to SEQ IOD NO:7 or nucleic acids encoding SEQ ID NO:8 and that "mediate male fertility" within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

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Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

See *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997) at pg 1406:

a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

... A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

... the claimed genera of vertebrate and mammal cDNA are not described by the general language of the '525 patent's written description supported only by the specific nucleotide sequence of rat insulin.

See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at page 1021:

A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

9. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is directed to a nucleotide sequence in a specific ATCC deposit. Since the nucleotide sequence is essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the nucleotide sequence is not so obtainable or available, a deposit of microorganism containing said nucleotide

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sequence may satisfy the requirements of 35 USC 112. The specification does not disclose a repeatable process to obtain the nucleotide sequence and it is not apparent if the nucleotide sequence is readily available to the public. Thus, for enablement purposes the deposit must be made under certain conditions.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has <u>not</u> been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,

(e) the deposit will be replaced if it should ever become inviable.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.801 - 1.809 [MPEP 2401-2411.05] for additional explanation of these requirements.

10. Claims 1, 3-4, 6-7, 9-15 and 27-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The claims are broadly drawn to a nucleic acid comprising the SBMu200 gene, SEQ ID NO:7, or hybridizing to SEQ ID NO:7, plant cells and plants transformed with it, a method of using it to "impact" the SBMu200 gene, expression vectors comprising the SBMu200 gene and an exogenous gene and a method of using the expression vectors to mediate male fertility in a plant.

The instant specification, however, only provides guidance for Mu mutagenesis of maize, and describes the isolation of SBMu200 male sterile plants (example 1); general guidance for cDNA library construction and RNA expression analysis (examples 2-3); guidance for sequencing of the SBMu200 genomic, SEQ ID NO:7, and cDNA clones, SEQ ID NO:1, which encode SEQ ID NO:2 and showing that the gene is expressed at certain points in microsporogenesis (example 4), and identification of the promoter, SEQ ID NO:5, in the genomic clone and deletion of analysis of the promoter (example 5).

The instant specification fails to provide guidance for a nucleic acid comprising the "SBMu200 gene" from any plant other than maize or a nucleic acid hybridizing to SEQ ID NO:7 and "mediating fertility", plant cells and plants transformed with it, a method of using it to "impact" the SBMu200 gene, expression vectors comprising the SBMu200 gene and an exogenous gene and a method of using the expression vectors to mediate male fertility in a plant.

The instant specification fails to provide guidance for "highly stringent" hybridization conditions that allow one to find the claimed nucleic acids, and it fails to provide guidance for which organisms have nucleic acids that mediate fertility and that hybridize to SEQ ID NO:7 under highly stringent conditions.

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The instant specification fails to provide guidance for which nucleotides of SEQ ID NO:7 can be altered and to which other nucleotides, and which nucleotides must not be changed, to maintain activity of the encoded protein and maintain the promoter activity within SEQ ID NO:7. The specification also fails to provide guidance for which nucleotides can be deleted and which regions of the nucleic acid can tolerate insertions and still produce a molecule.

Making "conservative" substitutions (e.g., substituting one polar amino acid for another, or one acidic one for another) in a protein does not produce predictable results. Lazar et al (1988, Mol. Cell. Biol. 8:1247-1252) showed that the "conservative" substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor alpha while "nonconservative" substitutions with alanine or asparagine had no effect (abstract). Similarly, Hill et al (1998, Biochem. Biophys. Res. Comm. 244:573-577) teach that when three histidines that are maintained in ADP-glucose pyrophosphorylase across several species are substituted with the "nonconservative" amino acid glutamine, there is little effect on enzyme activity, while the substitution of one of those histidines with the "conservative" amino acid arginine drastically reduced enzyme activity (see Table 1). The nucleic acids encoding all these mutated proteins, however, would hybridize under high stringency to the nucleic acids encoding the original protein.

The specification does not teach how to assay the function of the protein encoded by SEQ ID NO:7. Thus, one would not know how to determine if a nucleic acid that hybridizes to SEQ ID NO:7 encodes a protein with the same function as that encoded by SEQ ID NO:7.

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Claim 15 is drawn to targeted mutagenesis of the SBMu200 gene within a plant. The specification does not teach targeted mutagenesis of the SBMu200 gene within maize, much less in any other plant.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids that hybridize to SEQ ID NO:7. Making all possible single amino acid substitutions in an 588 amino acid long protein like that encoded by SEQ ID NO:7 would require making and analyzing 19⁵⁸⁸ nucleic acids; these proteins would have 99.8% identity to SEQ ID NO:2. Because nucleic acids that hybridize to SEQ ID NO:7 would encode proteins with many amino acid substitutions, many more than 19⁵⁸⁸ nucleic acids would need to be made and analyzed.

SEQ ID NO:7 also comprises a promoter sequence. Mutation of promoter sequences is also unpredictable; non-coding nucleic acid sequences that exhibit base pair deletions, substitutions or rearrangements, cannot be expected to maintain their promoter or enhancer activity. Donald et al (1990, EMBO J. 9:1717-1726) in a mutational analysis of the *Arabidopsis rbcS-IA* promoter found that the effect of a particular mutation was dependent on promoter fragment length (paragraph spanning pg 1723-1724). Hao, et al (1998, J. Biol. Chem. 273:26857-26861) investigated the binding activities of ethylene-responsive element-binding proteins (EREBP) to their cis-element GCC box (AGCCGCC). Creating base-pair substitutions within the GCC box modulates binding specificity, implying that different positions within the GCC box are important for differential binding by different EREBPs, in particular, substituting Ts for the two Gs eliminates binding completely (pg 26857, abstract and 26860, left column, 2nd paragraph).

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Constructing an antisense RNA sequence that reliably inhibits gene expression is an unpredictable science. Arndt et al (1997, Genome 40:785-797) teach that the ability of an antisense construct to inhibit RNA expression is dependent on the rate of transcription of the antisense RNA relative to that of the sense RNA, the localization of the antisense gene in the genome, and the length of complementarity between the sense and antisense RNA; in addition, the effect of the latter varies from gene to gene and organism to organism (pg 787, left column). Antisense constructs that are not completely homologous to the target gene can have very unpredictable effects. Colliver et al (1997, Plant Mol. Biol. 35:509-522) showed that transformation of bird's foot trefoil with a construct that was antisense to bean chalcone synthase resulted in transformants with *increased* levels of chalcone synthase transcripts (pg 519, left column, paragraph 2) and note other instances when this phenomenon has occurred (pg 519, right column, paragraph 1).

Plants of different species in which the expression of the same gene is inhibited via antisense constructs can behave very differently. While tomatoes containing an antisense acid invertase DNA construct grew identically to control plants (Klann et al, 1996, Plant Physiol. 112:1321-1330; see the abstract and pg 1323, right column, paragraph 1), carrot development is drastically altered when acid invertase expression is reduced via an antisense construct (Tang et al, 1999, Plant Cell 11:177-189; see pg 179, left column, paragraphs 1-2, and pg 184, left column, paragraph 1).

As the specification does not teach the transformation of any plant with a nucleic acid comprising SBMu200 gene, SEQ ID NO:7, or hybridizing to SEQ ID NO:7, undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed

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by the claims and plants transformed therewith, to identify those with altered male fertility, if such plants are even obtainable.

Given the claim breath, unpredictability in the art, undue experimentation, and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

- 11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 12. Claims 1, 3-4, 6-7, 9-15 and 27-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claims 1 and 12 are indefinite in their recitation of "the SBM200 gene". The term is not defined in the specification, nor is it a term of art. Claim 29 is similarly indefinite in its recitation of "SBMu200"

Claim 3 is indefinite in its recitation of "An isolated DNA molecule ... comprising a nucleotide sequence ... and those sequences which hybridize ...". Does the nucleotide sequence comprise both a nucleic acid of SEQ ID NO:1, 3 or 7 AND a nucleotide sequence that hybridizes to a nucleic acid that encodes SEQ ID NO:1, 3 or 7?

Claim 3 is indefinite in its recitation of "mediates fertility". It is entirely unclear what this means. "Mediates" means something acts through an intervening agency or exhibits indirect causation, connection or relation (Merriam-Webster Online Dictionary 2004, www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=mediate&x=26&y=12). What does this mean

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with respect to the function of the nucleic acid - it only appears that it has something indirect to do with fertility, but nothing about what it directly does is recited.

Claims 3 and 13 are indefinite in their recitation of "highly stringent conditions". The time, temperature and salt concentration of the hybridization and wash are not recited, and the term is not defined in the specification. Thus, the conditions are unclear.

Claims 6 and 9 lack antecedent basis for the limitation "the nucleotide sequence of claims 3" as claim 3 is drawn to a DNA molecule.

Claims 12-13 are indefinite in their recitation of "impacting". It is entirely unclear what one does to impact the gene. It is also unclear how doing anything to the gene, which may not even be <u>in</u> a plant, would affect the fertility of a plant.

Claim 13 is indefinite in its recitation of "A method of impacting fertility of a plant comprising impacting a nucleotide sequence in the plant encoding the amino acid sequence of any of SEQ ID NOs 2, or 4 the nucleotide sequences of any of SEQ. ID Nos. 1, 3, or 7 and those sequences...". First, words, or at least a comma, appear to be missing between "4" and "the". Second, does the method comprise "impacting" all three of a nucleotide sequence encoding SEQ ID NOs 2, or 4 AND SEQ. ID Nos. 1, 3, or 7 AND sequences that hybridize?

Claim 14 lacks antecedent basis for the limitation "the sequence expression".

Claim 15 lacks antecedent basis for the limitation "the nucleotide sequence" in line 1.

Claim 27 lacks antecedent basis for the limitation "the DNA sequence of claim 1" as claim 1 is drawn to a nucleotide sequence.

Claims 28-29 lack antecedent basis for the limitation "the promoter". In claim 29 it is unclear where this promoter is located relative to the promoter on the SBMu200 gene.

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It is unclear in claim 28 where the exogenous gene is located relative to the components of the SBMu200 gene. It is also unclear what the gene is exogenous to.

Claim 29 is not written in proper Markush format. The claims should be in the format "selected from the group consisting of A, B, C and D." A group "consisting essentially of" a list of promoters is indefinite because it is not clear what else is in the group. See MPEP § 2173.05(h). Additionally, "or" in line 2 should be replaced with --and--.

Claims 30 and 32 lack antecedent basis for the limitation "the exogenous gene" in lines 1 and 2, respectively.

Claim 31 is indefinite because more than one thing cannot be claimed in a claim. "cells" should be made singular and an article should start the claim.

Claim 32 lacks antecedent basis for the limitation "the promoter" in line 3.

Claim 33 lacks antecedent basis for the limitation "the regulatory element" in line 1.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 14. Claim 3 is rejected under 35 U.S.C. 102(a) as being anticipated by Walbot (2000, GenBank Accession Nos: AW519943 and AW424821).

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Walbot teach isolated nucleic acids that would hybridize to SEQ ID NO:7 under "highly stringent conditions" and would "meditate fertility in plants".

15. Claim 3 is rejected under 35 U.S.C. 102(a) as being anticipated by Anderson et al, 2000, GenBank Accession No: BE494080).

Anderson et al teach an isolated nucleic acid that would hybridize to SEQ ID NO:7 under "highly stringent conditions" and would "meditate fertility in plants".

16. Claims 1, 3-4, 6-7, 9-15, 27 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Albertsen et al (1998, US Patent 5,850,014).

Albertsen et al teach a nucleic acid that would hybridize to SEQ ID NO:7 under "highly stringent conditions"; this nucleic acid would be the "SBMu200" gene (see SEQ ID NO:1). Albertsen et al also teach plant cells and plants transformed by it, and a method of impacting fertility of a plant that would inherently "impacting" "SBMu200" gene by mutating it a repressing its expression (claims 1-6, column 8, line 24, to column 13, line 41).

17. Claims 28-33 are free of the priori art, given the failure of the prior art to teach or suggest an expression vector comprising the SBMu200 gene and a promoter operably linked to a nucleic acid that encodes a product that disrupts the function of male tissue, and a method of using it to mediate male fertility ion a plant. Claim 34 is free of the prior art, given the failure of the priori art to teach or suggest ATCC deposit No.98931.

Conclusion

18. No claim is allowed.

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19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (571) 272-0547.

Anne R. Kubelik, Ph.D. April 29, 2004

ANNE KLUELIM PATENT EXAMINER LUCO ACCIOCAL